REMARKS

Independent apparatus claim 1 has been amended to call for an adjustable back pressure regulator connected between the pressurized source and the demand valve to allow an operator to select an appropriate reference pressure to accommodate a patient's initial tolerance to positive lung pressures and subsequently increase the pressure to a maximum beneficial therapeutic level. Claims 25-30 have been cancelled and replaced by new claims 35-44, which claims call for an operator adjustable pressure regulator coupled to the demand valve for allowing the operator to set the reference pressure and change it during treatment (Claims 35-41) and further including a balanced inhalation valve (Claims 41-44).

The specification has been amended on page 8 to identify the inhalation/exhalation valve with the reference numeral 58 since the reference numeral 26 is used to identify the nebulizer. This page has also been amended to correct the numeral identifying the housing and identify the line 27 in accordance with Fig. 1. On page 9 the numeral 15a has been replaced by 15 (line 17), the nebulizer container has been given numeral 26a and numeral 29, referring to the tube connecting the face mask to the nebulizer output, has replaced numeral 25 to correspond with the drawings. Page 10 has been amended to correct the identification of the passageway 36e connecting the chambers 54b and 46c. Page 12 has been amended to correct the identification of the nebulizer nozzle 26c. The reference numeral 58, identifying the line connecting the output of the nebulizer to an input of valve 56, has been changed to 60 on pages 13, 14, and 15 since 58 identifies the balanced patient inhalation/exhalation valve depicted in Figures 17-19. Several reference numerals have been replaced on page 15 to correspond to the inhalation/exhalation valve parts shown in Figs. 17 and 18. Several numerals referring to various parts of the balanced inhalation/exhalation valve have been

corrected to correspond to Figs. 17 and 18 of the drawings.

Figs. 1, 3, 4, 7, 8, 13-15, 17 and 18 have been amended, as shown in red on the attached sheets, subject to the Examiner's approval, to conform to the specification with respect to the identification of various components, lines or passageways. Several lead lines have also been modified to correspond to the specification. Applicant apologizes for the misnumbering of several of the parts and passageways in the figures of the original drawings.

Enclosed herewith are copies of the references noted in the International Search Report recently received in the corresponding PCT application, i.e, U.S. Patent Nos: 4,821,767 (Jackson); 5,685,296 (Zdrojkowski et al); 5,464,009 (Tatarek-Gintowt); 5,357,950 (Wippler et al); and 5,245,997 (Bartos) as well as U.S. Patent No. 3,752,175 and 2,988,085, the latter references relating to altitude compensating pressure regulators for use with aircraft breathing devices. A copy of the International Search Report is also enclosed.

As noted by the report, the searcher considered that the claimed invention could not be considered novel or inventive in view of the Jackson and Zdrojkowski et al references. It is respectfully submitted that the claims presently in this application are not only novel, but clearly patentable over the apparatus disclosed in such references.

The Jackson reference discloses a demand valve with a pivotal partition for sensing the pressure in a user's face piece to connect and disconnect a supply of breathable gas to the face piece during the inhalation and exhalation phases of the breathing cycle. The chamber above the partition is vented to atmosphere or alternatively to some undisclosed reference pressure. There is no disclosure of an operator adjustable pressure regulator for setting the reference pressure (Indep. Claims 1, 35, 41.) or a nebulizer output (Claims 5, 37), or two pressure regulators for providing one

pressure for inhalation and a lower pressure for exhalation (Claims 14-20, 36), or a pressure gauge allowing the operator to see the actual reference pressure being applied (Claims 38, 42) or the combination including a patient's balanced inhalation/exhalation valve (Claim 41 et. seq.).

Patients often experience shock when suddenly confronted with a significant amount of gas pressure in their airway. To overcome this problem an urgent care giver, using the invention, can initially set the adjustable back pressure regulator to provide a relatively low reference pressure, e.g., 5 or less cm H_20 and subsequently increase the reference pressure to maximize the therapeutic effect when the patient is able to tolerate a higher pressure. The Jackson apparatus is not designed for CPAP procedures and even if it was used to provide a slight positive airway pressure there is no mechanism for an operator to see or set the pressure at a desired level or change the pressure during use. The apparatus claims are clearly patentable over Jackson.

The method of claim 22 which calls for varying the reference pressure during treatment is also missing from the Jackson teachings. Claims 31 et seq., directed to a novel balanced exhalation/exhalation valve, are also not taught or suggested in any of the references including the Jackson patent.

The Zdrojkowski et al patent describes a valve (12) for controlling the exhaust flow from a breathing circuit to nearly a constant value regardless of pressure. It is not a demand system, i.e., the pressurized source is not connected to or disconnected from the face mask 18 as a result of pressure changes. The apparatus as well as the method claims are clearly patentable over the Zdrojkowski et al reference.

The Bartos, Greg et al and Feathers references disclose various types of demand regulators of the positive or ambient pressure type with no means of adjusting the pressure to which the main

valve actuating mechanism responds without at least disassembling the valve from the breathing apparatus (see set screw 35 of Feathers). These references do not disclose an adjustable back pressure regulator connected to the pressurized source and the demand valve for setting the reference pressure (Claim 1) or indeed any apparatus which allows an operator to vary the reference pressure during treatment so that such operator may accommodate the positive pressure breathing tolerance of patient (Claims 35 et. seq.). The claims are patentable over these references for the reasons stated above.

The Tatarek-Gintowt , Wippler et al, Bartos, Gray et al and Feathers references were cited in the report as rendering the claims unpatentable when combined with other (undisclosed) references. The Colston , Fabish et al and Sanders et al references were cited as defining the general state of the art.

The Tatarek-Gintowt reference discloses a demand valve which may provides an output pressure above or below atmospheric. While the patentee depicts a screw 19 which apparently can adjust the pressure applied by leaf spring 17 and thereby regulate, to some extent, the pressure necessary to open or close the valve 10, the setting of such screw could only be changed by removing the valve from the breathing circuit and disassembling, at least, the outlet plate. While such a screw/spring arrangement may be broadly construed as a pressure regulator it is not an operator adjustable pressure regulator i.e., the setting of such a screw could not be changed by an operator during the treatment of a patent (Claim 35 et seq.) In addition, such a screw is not an adjustable back pressure regulator connected between the pressurized source and between a demand valve reference pressure chamber by supplying gas (at a reduced pressure) from the pressurized source to the reference chamber to set the reference chamber pressure (Claims 1-24). This reference does not

disclose a nebulizer output (Claims 5, 37), a bi-level reference pressure capability (Claims 14-20, 36), a balanced patient valve (Claims 31-34, 42 et seq.) or a method of varying the reference pressure during treatment (Claims 22-24.) The claims in this application are patentable over Tatarek-Gintowt.

The Wippler et al reference discloses a positive pressure demand valve for use by underwater divers, firemen etc. in which a bias spring (170) and screw (148) set the reference force, i.e, static set pressure of the regulator. The position of the screw 148 could only be changed by disassembling the valve as is the case of the Tatarek-Gintowt device. The pressure required to open/close the main valve (82) is not adjustable by the operator. The claims are patentable over the reference for the reasons given above.

The Colston reference describes an underwater breathing regulator that reduces the work of breathing through the use of venturi devices to increase pressure during inhalation and decrease pressure during exhalation. The pressure levels are a function of flow rate rather than an adjustable reference pressure. The outlet pressure is not adjustable nor does the reference describe a balanced patient valve.

The Sanders et al '269 patent as well as two additional Sanders et al patents, i.e., Nos. 5,148,802 and 5,433,193 ("'802 and '193 patents"), identified in applicant's Information Disclosure Statement, describe a BIPAP system (for sleep apnea patients) that use electronic sensors and signal conditioning devices to control pressure based on an algorithm that senses a change in flow rate to determine inhalation/exhalation phases. These patents do not disclose any apparatus for comparing the breathing appliance inlet pressure to a selected reference pressure to connect and disconnect a pressurized source of O_2 to a patient's breathing appliance. The claims are patentable over the Sanders et al patent.

The Fabish et al patent cited in the report as well as the Hamilton patent no. 5,787,882 are directed to conventional demand valve resuscitators and not to CPAP systems. No means is disclosed to provide continuous positive airway pressure or an adjustable airway pressure.

Patent No. 4,777,411 to Downs, identified in the Disclosure Statement, is directed to a CPAP system in which pressurized gas is continuously connected to a patient's face mask (and a pressure setting valve) instead of only on demand when the patient is inhaling. This type of prior art device is discussed in the background section of the specification. There is no demand valve.

Patent No. 4,655,214 identified in the Disclosure Statement relates only to a face mask.

Patent Nos. 2,988,085 and 3,752,175, identified in the Supplemental Disclosure Statement, relate to aneroid controlled demand valves in which the O_2 pressure in a pilot's face mask is changed in response to variations in ambient pressure, i.e., altitude. G-forces responsive demand valves are also used in conjunction with inflatable anti-g suits by pilots of high performance aircraft. The mask pressure would normally be constant during inhalation and exhalation at any given altitude with the aneroid or g-force load controller. However, bi-level systems have been proposed for the g-force controllers. Neither the aneroid nor the g-force systems are designed for CPAP use and will provide positive airway pressure only at relatively high altitudes or g-loads.

The portable gas powered CPAP apparatus as described and claimed in the application was approved by the Federal Drug Administration on July 15, 2002 and a single level unit, i.e, one reference pressure, was recently introduced to the market at the National Association of Emergency Medical Services Physicians ("NAEMSP") trade show by the exclusive licensee, Emergent Respiratory Products, a small start up company.

Applicant's undersigned counsel has been advised that the acceptance of the unit was extremely positive. A typical response to a demonstration of the unit at the trade show was voiced by a state medical director of a national company providing ambulance services. This director indicated that the low O_2 consumption rate and the absence of noise associated with O_2 escaping from the conventional bypass valve placed the unit at the head of the class of competitive portable CPAP products. This director, in charge of 250 ambulances in a single state, went on to indicate that (a) he believed that about 10% of his 400,000 annual call volume would receive CPAP therapy if a suitable portable system was available and (b) that he had reviewed, but not purchased, competitive units because of their large O_2 consumption and noise. After witnessing a demonstration of the invention he inquired as to how soon the company could deliver 250 of the units, one for each ambulance.

Emergent Respiratory Products has been inundated with orders since the trade show. Applicant will gladly provide evidence of the fact that the invention has filled a long felt need in providing emergency care, in the form of one or more declarations, if the Examiner believes that such evidence would be helpful in the examination of this application.

The claims now pending in this application are believed to clearly patentable over the prior art. If applicant's attorney can be of any further assistance please call the undersigned at the number provided.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 2, 2003.

May 2, 2003
Harold L. Jackson